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**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION**

CITY AND COUNTY OF SAN  
FRANCISCO, et al.,

Plaintiffs,

v.

PURDUE PHARMA L.P., et al.

Defendants.

Civil Case No.: 3:18-CV-07591-CRB

**DEFENDANT WALGREEN CO.'S  
NOTICE OF MOTION AND MOTION  
TO DISMISS FIRST AMENDED  
COMPLAINT AND MEMORANDUM  
OF POINTS AND AUTHORITIES**

*Declaration of Joshua D. Dick filed  
concurrently herewith*

Honorable Charles R. Breyer

Hearing Date: June 19, 2020  
Hearing Time: 10:00 AM  
Courtroom: 6 (17th Floor)

**TO ALL PARTIES AND THEIR COUNSEL OF RECORD:**

**PLEASE TAKE NOTICE THAT** on June 19, 2020, at 10:00 a.m., in the courtroom of the Honorable Charles R. Breyer, United States District Court for the Northern District of California, San Francisco Division, Courtroom 6 (17th Floor), 450 Golden Gate Avenue, San Francisco, California, or at another date and time to be set by the Court pursuant to the Court's Scheduling Order (Dkt. 142), Defendant Walgreen Co. ("Walgreens") will and hereby does move, pursuant to Rule 12(b) of the Federal Rules of Civil Procedure, for an order dismissing the First Amended Complaint brought by the City and County of San Francisco ("Plaintiffs"), on the ground that Plaintiffs lack standing and have failed to state a claim for public nuisance against Walgreens upon which relief may be granted. Walgreens' Motion is based on this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, the concurrently filed Declaration of Joshua D. Dick, any other matters of which the Court may take judicial notice, other documents filed in this action and incorporated herein, and any oral argument of counsel.

Dated: April 17, 2020

GIBSON, DUNN &amp; CRUTCHER LLP

By: /s/ Joshua D. Dick

Attorneys for Defendant WALGREEN CO.

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## MEMORANDUM OF POINTS AND AUTHORITIES

### SUMMARY OF ARGUMENT

Walgreens is uniquely situated in this case. It is the only pharmacy chain defendant among dozens of manufacturers and a number of wholesale distributors. Unlike the other distributor defendants, Walgreens does not distribute controlled substances—and has not since 2014. *See* First Am. Compl. (“FAC”) ¶ 553 (Doc. 128). Even back when Walgreens *did* distribute controlled substances, it only ever distributed to its own retail pharmacy stores, not to independent pharmacies, pain clinics, or “pill mills.” *See id.* Walgreens is unique in another way, as well: it is the only defendant against which Plaintiffs assert claims based on retail dispensing. It also is named in only one of Plaintiffs’ five claims: public nuisance.<sup>1</sup>

Walgreens is also a newcomer to the case. It was the only defendant added to the recently filed FAC—more than 14 months after Plaintiffs first brought this action and nearly a year after they amended their complaint to add 10 new parties (but not Walgreens) in the federal MDL. *See* Declaration of Joshua D. Dick in Support of Walgreen Co.’s Motion to Dismiss First Amended Complaint, Ex. A (City and County of San Francisco’s Short Form for Supplementing Complaint and Amending Defendants). It was only after the case was remanded from the Northern District of Ohio that Walgreens was added.<sup>2</sup>

With that backdrop, Plaintiffs’ public nuisance claim against Walgreens should be dismissed under both Rule 12(b)(1) and Rule 12(b)(6) of the Federal Rules of Civil Procedure.

First, Plaintiffs lack standing to bring their public nuisance claim under Article III because the alleged injury—an opioid epidemic in San Francisco—is not “fairly traceable” to Walgreens’ alleged conduct. *See Kaing v. Pulte Homes, Inc.*, No. 09-5057 SC, 2010 WL 625365 (N.D. Cal. Feb. 18, 2010), *aff’d sub nom. Kaing v. Pultegroup, Inc.*, 464 F. App’x 630 (9th Cir. 2011); *City of New Haven v. Purdue Pharma, L.P.*, No. X07HHDCV176086134S, 2019 WL 423990 (Conn. Sup. Ct. Jan. 8, 2019).

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<sup>1</sup> Walgreens has joined the Defendants’ Joint Brief as to the “law of the case,” public nuisance, and federal preemption arguments. As to Plaintiffs’ public nuisance theory based on Walgreens’ former distribution of prescription opioids, in an effort to conserve judicial resources Walgreens hereby incorporates by reference the arguments in the Motion to Dismiss filed by the Distributor Defendants.

<sup>2</sup> While Walgreens was not present when Plaintiffs made their request to this Court to once again amend their complaint following remand from the MDL, it is not aware of any reason why Plaintiffs could not have named Walgreens in the complaints they filed in December 2018 or April 2019.

Second, Plaintiffs have not pled, and cannot plead, necessary elements of a public nuisance claim: that Walgreens engaged in “affirmative conduct” beyond the mere distribution and sale of prescription opioids (or a failure to warn of their hazards) and that it did so with “actual knowledge” that its conduct would create the alleged public health hazard. *See Cty. of Santa Clara v. Atlantic Richfield Co.*, 137 Cal. App. 4th 292 (2006); *People v. ConAgra Grocery Prods. Co.*, 17 Cal. App. 5th 51 (2017).

Finally, Plaintiffs’ unique dispensing theory against Walgreens must fail for lack of an actionable duty. While the federal Controlled Substances Act (“CSA”) and its implementing regulations are not a valid source of duties for state tort liability, they are the sole basis for Plaintiffs’ dispensing theory. The Court should dismiss their claim for that reason alone. Plaintiffs’ theory also fails on its own terms, however. The CSA places the responsibility to evaluate the legitimacy of a prescription for controlled substances exclusively on the prescriber and the individual pharmacist filling the prescription—not on the corporate owner of a pharmacy, like Walgreens. Thus, none of Plaintiffs’ allegations about corporate-level systems, policies, or procedures could provide an actionable duty under the CSA.<sup>3</sup> This means the *only* way Walgreens could be liable to Plaintiffs for improper dispensing under the CSA (assuming a private right of action to enforce its duties) would be to hold it vicariously liable for actual, specifically identified dispensing violations by individual Walgreens pharmacists. But Plaintiffs do not even attempt to allege any dispensing violations by any Walgreens pharmacists in San Francisco.

## ARGUMENT

### **I. The Public Nuisance Claim Against Walgreens Should Be Dismissed for Lack of Standing**

Federal courts “have an obligation to assure [them]selves of litigants’ standing under Article III.” *Frank v. Gaos*, 139 S. Ct. 1041, 1046 (2019) (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 340 (2006)). “Standing to sue is a doctrine rooted in the traditional understanding of a case or controversy.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). Its purpose is to “ensure that federal courts do not exceed their authority as it has been traditionally understood.” *Id.* The three elements of Article III standing are: “The plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the

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<sup>3</sup> Should this case proceed to discovery, Walgreens will demonstrate that it has long had robust and industry-leading policies, procedures, and systems in place to guard against improper dispensing at its retail pharmacy stores. But that does not change the fact that CSA imposes no duty to do so.

1 challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.”  
 2 *Id.* (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). The burden is on Plaintiffs to  
 3 establish each of these elements. *Id.* At the pleading stage, Plaintiffs must have “clearly . . . allege[d]  
 4 facts demonstrating” each element. *Warth v. Seldin*, 422 U.S. 490, 518 (1975).

5 Under the causation prong of Article III standing, Plaintiffs’ alleged injury must be “fairly  
 6 traceable to the challenged action of the defendant, ***and not the result of the independent action of some***  
 7 ***third party not before the court.***” *Lujan*, 504 U.S. at 560-61.<sup>4</sup> Here, Plaintiffs have not come close to  
 8 satisfying this requirement. Plaintiffs seek to hold Walgreens responsible for a “public nuisance—*i.e.*, the  
 9 opioid epidemic” in San Francisco. *See* FAC ¶ 223. They concede that their alleged injury involves  
 10 “severe and far-reaching public health and social service consequences” stemming from “addiction” and  
 11 “overdose,” not only involving the kinds of prescription medications others manufactured and marketed,  
 12 and that Walgreens (among others) distributed and dispensed, but also and primarily “illicit drugs” like  
 13 heroin, fentanyl, and methamphetamine. *Id.* ¶¶ 16, 59, 68. As alleged, the crisis has affected every level  
 14 of government and government services, including “first responders, healthcare and other professionals,  
 15 and . . . even librarians.” *Id.* ¶ 19. The crisis also encompasses “one of the most complex issue[s] of our  
 16 time”: the combined challenges of “mental health,” “drug addiction,” and “homelessness” in San  
 17 Francisco. *See* City & County of San Francisco, California Mayor’s 2017-2018 & 2018-2019 Proposed  
 18 Budget, Mayor’s Office of Public Policy & Finance at 9, 15 (cited in FAC ¶ 58 & n.34).

19 But while Plaintiffs seek to hold Walgreens liable for these “widespread effects” of the alleged  
 20 opioid crisis, FAC ¶ 57, the alleged misconduct by Walgreens in this case is limited to contributing in  
 21 some way to an “oversupply of prescription opioids” in San Francisco as a distributor (until 2014) and a  
 22 dispenser, *id.* ¶ 555, in violation of alleged duties under the CSA and its regulations, *id.* ¶¶ 894, 897.  
 23 Plaintiffs do not (and cannot) allege that Walgreens ever manufactured, marketed, or promoted a single  
 24 opioid. They concede that Walgreens stopped distributing opioids in San Francisco in 2014. *Id.* ¶ 555.  
 25 Plaintiffs have not identified a single pharmacy order they contend a Walgreens warehouse should not  
 26 have shipped or a single prescription they contend a Walgreens pharmacist should not have filled.

27  
 28 <sup>4</sup> All emphases are added unless otherwise noted.



1 Plaintiffs do not even begin to link together the lengthy causal chain between any (unidentified)  
 2 specific acts by Walgreens and (1) instances of actual diversion of prescription opioid medications outside  
 3 of legitimate medical channels; (2) abuse of those prescription drugs; (3) addiction or other health-related  
 4 effects resulting from that abuse; (4) a transition to abuse of illegal “street drugs” like heroin, imported  
 5 illicit fentanyl, or methamphetamine; (5) overdoses or death from that abuse of illegal drugs; and (6) a  
 6 resulting increased and ongoing demand on emergency, social, and other government services. That is  
 7 not all, however. Plaintiffs’ already extremely attenuated causal chain must further account for, among  
 8 many other factors, the role of (a) action or inaction by federal and state regulators; (b) drug marketing  
 9 and promotion; (c) medical prescribing and over-prescribing; (d) distribution of controlled substances by  
 10 other distributors; (e) dispensing by non-Walgreens pharmacists in San Francisco, including pharmacists  
 11 working for pain clinics and pill mills; (f) diversion of legitimate prescriptions, after they are dispensed  
 12 by Walgreens and other pharmacies, by friends or family members of patients; (g) criminal activity by  
 13 individual drug users, drug dealers, and drug cartels operating in and around San Francisco; (h) underlying  
 14 mental health and substance abuse issues; (i) chronic health conditions; (j) economic factors, including  
 15 unemployment and homelessness; (k) unrelated budgetary constraints; (l) action or inaction by state or  
 16 local law enforcement; and (m) government management (or mismanagement).

17 Plainly, then, Plaintiffs’ alleged injuries are not “fairly traceable” to Walgreens’ alleged conduct.  
 18 To the contrary, Plaintiffs themselves describe their causation theory as depending on “[t]he effects of  
 19 Defendants’ wrongful conduct” causing still more “ripple effects.” FAC ¶ 59 (identifying the “ripple  
 20 effects” as “heroin, fentanyl, and methamphetamine use, morbidity, and mortality”). This type of effects-  
 21 of-effects causation theory is far outside the bounds of Article III, necessarily depending on a dizzying  
 22 array of complex social, political, economic, medical, and epidemiological factors and the actions of  
 23 innumerable third parties not before this Court. The causal chain cannot be stretched so far.

24 For example, in *Kaing v. Pulte Homes, Inc.*, 2010 WL 625365 (N.D. Cal. Feb. 18, 2010), *aff’d sub*  
 25 *nom. Kaing v. Pultegroup, Inc.*, 464 F. App’x 630 (9th Cir. 2011), another court in this district dismissed  
 26 the plaintiff’s primary theory of recovery based on the “causation element of standing.” *Id.* at \*6. The  
 27 court held that a decline in value of the plaintiff’s home was not “fairly traceable” to the defendant  
 28 developer’s practice of selling other homes in the neighborhood to unqualified buyers because any loss

1 was “dependent on many factors,” including “unemployment, health problems, a general weakening  
 2 economy, [and] other financial conditions,” and “necessarily depend[ed] upon a causal chain that includes  
 3 numerous individual decisions” of absent third parties. *Id.* The number of factors and the length of the  
 4 causal chain in *Kaing* pale in comparison to this case. The result should be the same.<sup>5</sup>

5 Likewise, the court presiding over opioid litigation in Connecticut held that the city plaintiffs  
 6 lacked standing to bring lawsuits “derived from harms allegedly connected to defendants by lengthy,  
 7 multifaceted chains of causation,” forcing courts to try to “separate that conduct from the myriad of  
 8 independent factors that make up most broadly defined social crises.” *City of New Haven v. Purdue*  
 9 *Pharma, L.P.*, No. X07HHDCV176086134S, 2019 WL 423990, at \*3 (Conn. Super. Ct. Jan. 8, 2019). To  
 10 conclude otherwise, the court explained, would sanction “causation by conjecture.” *Id.* at \*2. Of course,  
 11 all actions have “indirect effects on others like the rock that ripples the pond.” *Id.* at \*3. But the cities’  
 12 alleged injuries—“the social spin off of rising addiction rates”—were “a long radius and many concentric  
 13 circles away” from any cognizable form of direct injury under the law. *Id.* at \*7.

## 14 **II. The Public Nuisance Claim Should Be Dismissed Because Plaintiffs Have Not Alleged Any** 15 **“Affirmative Conduct” by Walgreens with Knowledge of the Alleged Hazard**

16 To be held liable for public nuisance under California law a defendant must both (1) engage in  
 17 “affirmative conduct” beyond the mere manufacture, distribution, or sale of a product or failure to warn  
 18 of its hazards and (2) act “with knowledge of the public health hazard that this [conduct] would create.”  
 19 *Cty. of Santa Clara v. Atlantic Richfield Co.*, 137 Cal. App. 4th 292, 309-10 (2006). As explained in  
 20 *People v. ConAgra Grocery Prods. Co.*, 17 Cal. App. 5th 51 (2017), “[i]f . . . defendants ***did not promote***  
 21 **lead paint for interior residential use, or *did not know*** at the time they did so that such use would create a

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24 <sup>5</sup> See also, e.g., *Maya v. Centex Corp.*, 658 F.3d 1060, 1070 (9th Cir. 2011) (“In cases where a chain of  
 25 causation ‘involves numerous third parties’ whose ‘independent decisions’ collectively have a  
 26 ‘significant effect’ on plaintiffs’ injuries, the Supreme Court and this court have found the causal chain  
 27 too weak to support standing at the pleading stage.” (quoting *Nat’l Audubon Soc., Inc. v. Davis*, 307  
 28 F.3d 835, 849 (9th Cir. 2002); *Allen v. Wright*, 468 U.S. 737, 759 (1984)); *Cal. Advocates for Nursing*  
*Home Reform, Inc. v. Chapman*, 2013 WL 5946940, \*7 (N.D. Cal. Nov. 5, 2013) (to meet their burden  
 to establish standing at the pleading stage, plaintiffs “must allege ***specific, concrete facts***” that show  
 with “***substantial probability***” that the defendant’s conduct caused the alleged injury”).

1 public health hazard, those promotions would not establish that defendants created or assisted in the  
2 creation of a public nuisance.” *Id.* at 93. Plaintiffs’ claim against Walgreens fails on both counts.

3 **A. Walgreens never marketed or promoted prescription opioids and did not engage in**  
4 **any other “affirmative conduct” that would give rise to a public nuisance claim.**

5 California courts have permitted public nuisance claims based on the manufacture, distribution, or  
6 sale of lawful products only where the plaintiff has alleged that the defendant engaged in “affirmative  
7 promotion” of those products. *See ConAgra*, 17 Cal. App. 5th at 83-84. In this case, while Plaintiffs  
8 allege that *other* defendants promoted prescription opioids, *see* FAC ¶¶ 225-546 (describing allegedly  
9 misleading promotion by certain manufacturers), they allege no such promotion by Walgreens. Nor could  
10 they. Walgreens has never marketed or promoted prescription opioids. Rather, until mid-2014, Walgreens  
11 *distributed* controlled substances to its own retail pharmacy locations—not to independent pharmacies,  
12 pain clinics, or “pill mills”—and its licensed pharmacists *dispense* lawful, FDA-approved medications  
13 pursuant to prescriptions written by licensed medical prescribers. Plaintiffs do not and cannot allege any  
14 “affirmative steps” by Walgreens that satisfy the requirements of *Santa Clara* and *ConAgra*.

15 **B. Walgreens never acted with actual knowledge of the alleged public health hazard.**

16 Plaintiffs also have not alleged that Walgreens possessed the knowledge required to support public  
17 nuisance liability. Constructive knowledge—what a defendant allegedly “should have known”—is not  
18 enough. *ConAgra*, 17 Cal. App. 5th at 83-85. To state a claim for public nuisance, Plaintiffs must allege  
19 that Walgreens had “actual knowledge” that its conduct would create “the public health hazard” on which  
20 the claim is based. *Id.* at 83-85, 93; *see also Santa Clara*, 137 Cal. App. 4th at 309-10.

21 Plaintiffs’ cannot meet that requirement. The most Plaintiffs can point to are conclusory  
22 allegations that Walgreens “allowed widespread diversion to occur—and it did so knowingly,” FAC ¶ 564,  
23 or that Walgreens “was, or should have been, fully aware that the quantity of opioids it was both  
24 distributing and dispensing was untenable,” *id.* ¶ 571. Indeed, the vast majority of Plaintiffs’ allegations  
25 are that Walgreens *failed* to use data that might have given it certain knowledge. *See* FAC ¶¶ 563, 567-  
26 68 (alleging that certain data “allowed” Walgreens to observe “potentially suspicious” patterns but that  
27 Walgreens “failed to adequately use” or “analyze” the data). None of these allegations come close to  
28

supporting a finding that Walgreens possessed *actual knowledge* that its conduct would result in the alleged public health hazard—“*i.e.*, the opioid epidemic,” *id.* ¶ 223—underlying Plaintiffs’ claim.

### III. The Public Nuisance Claim Based on *Dispensing* Should Also Be Dismissed Because Plaintiffs Have Not Identified Any Dispensing Duty Owed by Walgreens

The elements of a California public nuisance claim include “the existence of a duty.” *Melton v. Boustred*, 183 Cal. App. 4th 521, 542 (2010); *see also In re Firearm Cases*, 126 Cal. App. 4th 959, 988 (2005) (“The language of the Restatement presumes that the necessary elements for proof of a cause of action for public nuisance include the existence of a duty and causation.”).

Plaintiffs seek to hold Walgreens liable for public nuisance as both a distributor *and* as a dispenser of prescription opioid medications. The distinction between those two types of conduct is critical. Unlike the statutory and regulatory requirements for *distribution*—obligations that run directly to the registered entity and require maintenance of systems, policies, and procedures at the corporate level—the statutory and regulatory requirements for *dispensing* apply only to individual pharmacists in the exercise of their professional judgment at the pharmacy dispensing counter. Plaintiffs alternate between acknowledging, blurring, and ignoring this distinction—but they cannot escape it.

Acknowledging this critical distinction at times, Plaintiffs allege that, “[u]nder the CSA, *pharmacists* are charged with a ‘corresponding responsibility’ to dispense only legitimate prescriptions and implement effective controls and procedures to prevent diversion.” FAC ¶ 559. And Plaintiffs go on to assert that “[p]harmacy owners . . . are also liable for *their pharmacists’ CSA violations*.” *Id.* ¶ 560. But Plaintiffs have not alleged any facts that even arguably give rise to vicarious liability for Walgreens based on any improper dispensing by any Walgreens pharmacist in San Francisco. That is because, among other reasons, Plaintiffs have failed to identify a single Walgreens pharmacist in San Francisco, much less identified any prescription that a Walgreens pharmacist purportedly filled in violation of the CSA.

At other points in the Complaint, Plaintiffs attempt to blur the distinction, describing the CSA duties that are owed solely by *pharmacists* as duties owed by *pharmacies*. *See, e.g., id.* ¶ 561 (“The DEA, among others, has provided extensive guidance to *pharmacies* concerning their duties to the public. The guidance advises *pharmacies* how to identify suspicious orders and other evidence of diversion.”). But not only does federal law refrain from obligating anyone other than the individual pharmacist presented

1 with a prescription to question the validity of that prescription, California law expressly forbids the  
 2 imposition of such a duty. California Board of Pharmacy regulations state that “[o]nly a *pharmacist*” is  
 3 permitted to “evaluate . . . a prescription” or perform any function “requir[ing] professional judgment.”  
 4 CAL. CODE REGS., tit. 16, § 1793.1. Nor does California law provide any room for Plaintiffs’ attempted  
 5 blurring of the roles of a “pharmacist” and his or her pharmacy employer. A “pharmacist” is expressly  
 6 defined as a “*natural person*,” not a legal person or entity. *See* CAL. BUS. & PROF. CODE § 4036.

7 Finally, in other places, Plaintiffs simply ignore the distinction between pharmacists and  
 8 pharmacies, inventing corporate-level duties that do not exist and for which they cannot cite any legal  
 9 authority. *See* FAC ¶¶ 563-69. Those duties cannot be found in the CSA or its regulations, and would  
 10 necessarily usurp pharmacists’ professional judgment in contravention of federal and state law.

11 The sections below explain in greater detail how the CSA imposes its dispensing obligations on  
 12 individual pharmacists—not pharmacy corporations—and why Plaintiffs come nowhere close to  
 13 adequately alleging that any Walgreens pharmacist in San Francisco violated those duties.

14 **A. The CSA and its implementing regulations impose duties on individual *pharmacists***  
 15 **not corporate-level duties on pharmacies or pharmacy corporations.**

16 The sole source of any dispensing-related duties identified by Plaintiffs is the federal CSA and its  
 17 implementing regulations.<sup>6</sup> Thus, despite the fact the CSA clearly is *not* a valid source of duties for  
 18 liability under state law, *see, e.g., Smith v. Hickenlooper*, 164 F. Supp. 3d 1286, 1290-91 (D. Colo. 2016),  
 19 Plaintiffs’ dispensing theory hinges entirely on the contours of those CSA “duties” and whether Walgreens  
 20 violated them. The Court can and should dismiss the dispensing theory for this reason alone.

21 Even if there was a private right of action under the CSA, however, Plaintiffs’ claim would fail

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23 <sup>6</sup> *See, e.g.,* FAC ¶ 559 (“Under the CSA, pharmacists are charged with a ‘corresponding responsibility’  
 24 to dispense only legitimate prescriptions and implement effective controls and procedures to prevent  
 25 diversion.”); *id.* ¶ 894 (alleging that Walgreens “unreasonably interfered with the public health, safety,  
 26 peace and comfort of San Francisco’s residents by failing to ensure it dispensed only legitimate opioid  
 27 prescriptions and failing to implement effective controls and procedures to prevent diversion” and citing  
 28 21 C.F.R. § 1301.71(a) and 21 C.F.R. § 1306.04(a)); *id.* ¶ 897 (alleging that “Walgreens’ conduct  
 includes the filling of prescriptions in the presence of factors questioning the legitimacy of the  
 prescription or the prescriber in violation of 21 C.F.R. § 1306.04”); *see also* ¶ 560 (alleging that  
 “[p]harmacy owners . . . are also liable for their pharmacists’ CSA violations”).

1 nonetheless. Indeed, Plaintiffs have not identified a single provision of the CSA or any of its enabling  
 2 regulations that makes pharmacy corporations responsible for questioning facially valid prescriptions  
 3 written by registered medical practitioners. This is not surprising, because no such provisions exist. While  
 4 the CSA instructs that DEA’s registration decisions for *manufacturers* and *distributors* consider their  
 5 “maintenance of effective controls against diversion of particular controlled substances,” 21 U.S.C. § 823  
 6 (a)(1), (b)(1), (d)(1), (e)(1), the statute does not list any such factor for *pharmacies*, *id.* § 823 (f)(1)-(5).  
 7 Congress clearly knew how to indicate an expectation that an entity affirmatively maintain effective  
 8 controls against diversion—it did so *four times* in § 823 for every other type of registrant. Yet Congress  
 9 chose not to impose that additional layer of responsibility on pharmacies. Similarly, DEA regulations  
 10 requiring registrants to “design and operate a system” to identify “suspicious orders of controlled  
 11 substances,” applies to *distributors* not *pharmacies*. 21 C.F.R. § 1301.74 (a)-(b).<sup>7</sup>

12 The obligation to evaluate a prescription resides not at the corporate level but with the individual  
 13 pharmacist when the pharmacist is presented with a prescription. The regulation could not be clearer:  
 14 “The responsibility for the proper prescribing and dispensing of controlled substances is upon the  
 15 prescribing practitioner, but a corresponding responsibility rests with *the pharmacist who fills the*  
 16 *prescription.*” *Id.* § 1306.04. Thus, the regulatory text assigns primary responsibility for ensuring the  
 17 proper prescribing and dispensing of controlled substances to the prescribing practitioner and a  
 18 “corresponding” responsibility to the “pharmacist” who fills the prescription. Like California law, DEA  
 19 regulations define “pharmacist” as a state-licensed professional *individual*, not a pharmacy corporation.  
 20 21 C.F.R. § 1300.01; CAL. BUS. & PROF. CODE § 4036. The regulation’s description of a pharmacist’s  
 21 responsibility as “corresponding” to the responsibility of the “prescribing practitioner” reinforces the  
 22

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23 <sup>7</sup> Plaintiffs cite 21 C.F.R. § 1301.71, which requires all registrants to provide effective controls to guard  
 24 against theft and diversion of controlled substances. But with respect to pharmacies, this regulation only  
 25 imposes requirements for in-store physical security controls and has never been understood to require a  
 26 “system” for disclosing “suspicious orders of controlled substances,” *id.* § 1301.74 (a)-(b) (applying this  
 27 requirement only to distributors of controlled substances); *see also, e.g., ChipRX, L.L.C., d/b/a City*  
 28 *Center Pharmacy*, 82 Fed. Reg. 51,433-02, 51,434 (DEA Nov. 6, 2017) (pharmacy was alleged to have  
 failed to maintain effective controls against diversion and theft where the pharmacist-in-charge was  
 routinely stealing controlled substances to fuel his own addiction and deleting surveillance video footage  
 of his unlawful removal of controlled substances from the pharmacy premises).



1 conclusion that the obligation rests with the pharmacist and not the corporate owner of a pharmacy. The  
 2 responsibilities are both *professional* in nature—demanding the exercise of specialized judgment by a  
 3 professional who has earned the required degree and is trained and licensed in a regulated discipline.

4 Decades of agency practice confirm that any regulatory obligation to determine whether a  
 5 prescription was not written for a legitimate medical purpose rests exclusively with the pharmacist  
 6 presented with that prescription. *See, e.g., Bob’s Pharmacy & Diabetic Supplies*, 74 Fed. Reg. 19,599-  
 7 03, 19,601 (DEA April 29, 2009) (“DEA has long interpreted [21 C.F.R. § 1306.04(a)] ‘as prohibiting a  
 8 **pharmacist** from filling a prescription for a controlled substance when he either knows or has reason to  
 9 know that the prescription was not written for a legitimate medical purpose.’” (quoting *Medicine Shoppe-*  
 10 *Jonesborough*, 73 Fed. Reg. 364-01, 381 (DEA Jan. 2, 2008)); *Edge Pharmacy*, 81 Fed. Reg. 72,092-03,  
 11 72,111 (DEA Oct. 19, 2016) (“[T]o prove a violation of the corresponding responsibility, the Government  
 12 must show that **the pharmacist** acted with the requisite degree of scienter.”).

13 All of this explains why Plaintiffs’ haphazard allegations that Walgreens has a corporate-level duty  
 14 to enact specific systems, policies, or procedures to prevent improper dispensing cannot be reconciled  
 15 with the source of law on which Plaintiffs rely. The CSA and its implementing regulations nowhere  
 16 impose a duty (1) to “gather[], consolidate[], and analyze[]” dispensing data, FAC ¶ 563; (2) to implement  
 17 or refrain from implementing a particular “compensation system” for pharmacists, *id.* ¶ 565; (3) to provide  
 18 additional training for “pharmacists and pharmacy technicians,” *id.* ¶ 566; (4) to “use data” to identify  
 19 doctors “writing suspicious volumes of prescriptions” or to “avoid filling prescriptions that were illegally  
 20 diverted,” *id.* ¶ 567; (5) to conduct specific analyses of prescription sales across stores, drugs, and time,  
 21 *id.* ¶ 568; or (6) to conduct “internal or external audits” of pharmacy sales, *id.* ¶ 569.

22 The reason the CSA and its implementing regulations do not say any of those things is because the  
 23 dispensing of controlled substances is and must be an exercise of professional judgment, prescription-by-  
 24 prescription, by a licensed and trained pharmacist. *See* 21 C.F.R. § 1306.04 (a). So, for example, even if  
 25 Walgreens aggregated and analyzed data in all the ways Plaintiffs allege it should, each Walgreens  
 26 pharmacist would still be required by law to exercise his or her professional judgment—*i.e.*, his or her  
 27 “corresponding responsibility”—when filling each opioid prescription for each patient and could not rely  
 28 on the presence or absence of corporate policies or procedures in lieu of that judgment. Any so-called

1 duty that would require a non-pharmacist to override the judgment of a pharmacist is contrary to federal  
 2 and state law. *See, e.g.*, CAL. CODE REGS., tit. 16, § 1793.1 (“Only a pharmacist” is permitted to “evaluate  
 3 . . . a prescription” or perform any function “requir[ing] professional judgment.”).

4 **B. Plaintiffs cannot hold Walgreens liable for improper dispensing because they have**  
 5 **not identified a single instance of a Walgreens pharmacist in San Francisco**  
 6 **knowingly filling a prescription written for an illegitimate purpose.**

7 Even though the duties related to evaluating the legitimacy of a prescription rests with the  
 8 dispensing pharmacist, Plaintiffs have not adequately pleaded a violation of those duties by any Walgreens  
 9 pharmacist in San Francisco. As interpreted by DEA, “to prove a violation of the corresponding  
 10 responsibility” requires a showing that “the pharmacist acted with the requisite degree of scienter.”  
 11 *Superior Pharmacy*, 81 Fed. Reg. 31,310-01, 31,335 (DEA May 18, 2016). A violation of a pharmacist’s  
 12 corresponding responsibility requires a finding that the pharmacist either (1) filled a prescription despite  
 13 “actual knowledge that the prescription lacked a legitimate medical purpose” or (2) was “willfully blind  
 14 (or deliberately ignorant) to the fact that the prescription lacked a legitimate medical purpose.” *Id.*; *see*  
 15 *also E. Main St. Pharmacy*, 75 Fed. Reg. 66,149-01, 66,150 (DEA Oct. 27, 2010) (“[W]hen prescriptions  
 16 are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes  
 17 and thereby avoid actual knowledge of the real purpose of the prescription.”). “Willful blindness” is a  
 18 stringent standard. The U.S. Supreme Court has explained that the doctrine prevents parties from  
 19 “deliberately shielding themselves from clear evidence of critical facts that are strongly suggested by the  
 20 circumstances.” *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011).

21 The statutory and regulatory context surrounding § 1306.04 confirms this high bar. In addition to  
 22 defining and assigning the corresponding responsibility to pharmacists, § 1306.04 interprets the CSA’s  
 23 requirement that controlled substances be dispensed only upon a legitimate prescription. *See* 21 U.S.C.  
 24 § 829. The second sentence of § 1306.04(a) provides that the existence of a prescription for controlled  
 25 substances does not prevent an individual from violating the CSA if that person fills the prescription when  
 26 he or she *knows* it is illegitimate. *See id.* (“An order purporting to be a prescription issued not in the usual  
 27 course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C.  
 28



§ 829] and the person *knowingly* filling such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.”).<sup>8</sup>

Plaintiffs’ suggestion that mere negligence or suspicion is sufficient to give rise to pharmacist liability under the CSA, *e.g.*, FAC ¶¶ 562, 577, 897, is thus clearly incorrect. It is manifestly not enough to assert that pharmacists may have filled prescription despite so-called “red flags.” The term “red flags” does not appear in the CSA or its regulations, but is a shorthand used by DEA in certain administrative proceedings for indicia that might give a pharmacist reason to suspect that a specific prescription was not legitimate. But even “proof that a pharmacist dispensed a controlled substance prescription without resolving a red flag which only created a ‘reasonable suspicion’ that the prescription lacked legitimate medical purpose, is not enough to establish that a pharmacist acted with the requisite scienter” to establish a violation of the regulations. *Superior Pharmacy*, 81 Fed. Reg. at 31,335 n.54.<sup>9</sup>

So while Plaintiffs may be correct that “[p]harmacy owners” can be subject to vicarious liability for “their pharmacists’ CSA violations” in some circumstances, FAC ¶ 560, Plaintiffs never allege that any Walgreens pharmacist in San Francisco ever knowingly filled an opioid prescription that lacked a legitimate medical purpose.<sup>10</sup> This is fatal to any theory of derivative liability as a matter of law and logic.

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<sup>8</sup> This means that, even if pharmacists’ CSA duties *did* apply to pharmacy corporations (and they do not), Plaintiffs still have not adequately pleaded a violation. Any such duty would be limited to a duty not to *knowingly* fill a specific prescription written by a practitioner acting outside the usual course of professional practice. *See generally* 21 C.F.R. § 1306.04(a). But Plaintiffs nowhere allege that Walgreens (or any of its employees) *knowingly* filled any specific prescriptions written outside the usual course of professional practice in San Francisco. They do not identify any specific prescriptions at all. General allegations about diversion, the ability (or failure) to analyze data, or mere suspicion based on aggregate volume across chain stores simply do not suffice. *See* FAC ¶¶ 556, 563, 564, 567, 571.

<sup>9</sup> Were the requirements under the CSA what Plaintiffs suggest, they would be in conflict with California law governing the practice of pharmacy, which provides in relevant part that “[n]o licentiate shall obstruct a patient in obtaining a prescription drug . . . that has been legally prescribed or ordered for that patient” and that “[n]otwithstanding any other provision of law, a licentiate shall dispense drugs . . . pursuant to a lawful order or prescription unless . . . [b]ased solely on the licentiate’s professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug . . . would cause a harmful drug interaction or would otherwise adversely affect the patient’s medical condition.” *See* CAL. BUS. & PROF. CODE § 733.

<sup>10</sup> “Nothing which is done or maintained under the express authority of a statute can be deemed a nuisance.” CAL. CIV. CODE § 3482. Because Walgreens pharmacists dispensed prescription opioid

A principal cannot be sued for its agent's tort absent allegations sufficient to show that the agent violated a cognizable duty to the plaintiff in the first place. *See Lisa M. v. Henry Mayo Newhall Memorial Hospital*, 12 Cal. 4th 291, 296-97 (1995) ("The rule of respondeat superior is familiar and simply stated: an employer is vicariously liable for *the torts* of its employees committed within the scope of the employment."); *Doe v. Roman Catholic Archbishop of L.A.*, 247 Cal. App. 4th 953, 969 (2016) ("[A] principal may be liable for the *wrongful conduct* of its agent . . ."); cf. *Lehmuth v. Long Beach Unified School Dist.*, 53 Cal. 2d 544, 550 (1960) (where vicarious liability is premised on the tortious conduct of an agent, "a verdict releasing the agent from liability releases the principle").<sup>11</sup>

### CONCLUSION

For the foregoing reasons, the Court should dismiss Plaintiffs' public nuisance claim against Walgreens in its entirety under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6).

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Respectfully submitted,

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medications under the CSA, and since Plaintiffs have not alleged any CSA violation by any Walgreens pharmacist, Plaintiffs' nuisance claim as to dispensing fails for this reason as well.

<sup>11</sup> It is of course not remotely enough for Plaintiffs to rely on allegations about enforcement actions involving Walgreens pharmacists outside of San Francisco. *See* FAC ¶ 574 (discussing a 2009 order to show cause issued by DEA to a Walgreens pharmacy in San Diego); *id.* ¶ 576 (discussing a 2013 settlement with DEA involving allegations against six Walgreens pharmacies in Florida). Even if those allegations supported an inference that a Walgreens pharmacist *knowingly* filled an illegitimate opioid prescription, none has any alleged connection to Plaintiffs' and their claimed injuries.

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**CERTIFICATE OF SERVICE**

I, Joshua D. Dick, certify that on April 17, 2020, I electronically filed the foregoing with the Clerk of this court by using CM/ECF system, which will accomplish service through the Notice of Electronic Filing for parties and attorneys who are Filing Users.

By: /s/ Joshua D. Dick

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